

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

BRUCE N. SAFFRAN, Ph.D., M.D.,  
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION.  
Defendant.

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CIVIL ACTION NO. 2-05-CV-547 (TJW)

**MEMORANDUM OPINION AND ORDER**

**I. Introduction**

The court DENIES Boston Scientific Corporation's ("BSC") Motion for Judgment as a Matter of Law, or, in the Alternative, for a New Trial (#180) (the "Motion") for the reasons addressed in this opinion.

**II. Factual Background and Procedural Posture**

In this patent infringement case, the plaintiff, Bruce Saffran ("Saffran") Ph.D., M.D., sued BSC for infringing, directly and/or contributorily, claims 1-4, 6-11, 13, and 15-18 (the "Asserted Claims") of United States Patent No. 5,653,760 (the "'760 patent"). After considering the parties' claim construction proposals, filed pursuant to a scheduling order, the court issued a claim construction opinion on September 28, 2007 ("*Markman* Order"). At the claim construction phase of this trial, the parties disagreed about the claim terms that the court should construe for the jury. The court agreed with the plaintiff that some of the terms BSC asked the court to construe did not need construction. To construe those terms, the court would have been forced to either improperly import limitations from the specification or choose a definition from multiple extrinsic dictionary definitions with no basis in the specification or record for selecting one of the definitions.

After the court issued the *Markman* Order, BSC filed multiple motions for summary

judgment and suggested in those motions that it did not agree with the court's claim constructions.

BSC filed a formal request for supplemental claim construction on January 24, 2008—roughly two weeks from the trial date (#142). Aside from statements in its dispositive motions, the January 24 request was the only supported request BSC made to alter or amend the court's claim constructions. In BSC's request for supplemental claim construction, BSC asked the court to hold that Saffran disclaimed open mesh stent structures during prosecution of the '760 patent and rule that the "minimally porous" and "substantially restricting" limitations exclude the open mesh stent structure of the accused products (the "Taxus Stents"). The record did not support BSC's requests, so the court denied them.

However, in the process of denying BSC's requests, the court resolved a key claim construction dispute between the parties. One of BSC's non-infringement theories was that the '760 patent did not encompass an open mesh stent structure because, *inter alia*, BSC believed that the '760 patent claimed a "sheet" to be wrapped around the stent structure and that Saffran disclaimed an open mesh stent structure. The court resolved this claim scope dispute by rejecting BSC's argument that Saffran disclaimed an open mesh stent structure and by refusing to limit the claimed invention to a "sheet"—BSC asked the court to construe the term "device" in the preamble of claims 1, 8, and 15 as a "sheet." In rejecting BSC's limitation of the claimed invention, the court found that BSC's proposed construction ignored several embodiments described in the patent specification.

The court revisits the claim construction history of this case because BSC tried to informally circumvent the court's claim construction rulings in its motions for summary judgment, motions *in limine*, and expert reports. *See, e.g.*, Docket Nos. 69, 96, 107, 123, 126, 139, and 197. Although BSC commented in various briefs that it did not agree with the court's claim constructions, it did

not file a motion for reconsideration at those times. *See id.* To make matters worse, BSC's proposed constructions and supporting arguments changed as the case progressed. The net effect of BSC's shifting-sands approach was to provide the court a "moving target" with respect to claim construction. The trial began on February 5, 2008 and the jury reached a verdict on February 11, 2008 in which it determined that BSC infringed the Asserted Claims directly and/or contributorily. The jury did not find any of the Asserted Claims invalid and BSC now files a motion for judgment as a matter for law. The claim construction positions taken in the Motion differ still from BSC's prior positions. Thus, ironically, many of BSC's claim construction proposals made throughout this case are, as a matter of law, incorrect according to BSC's arguments in the Motion.

### **III. Legal Standard**

Pursuant to Federal Rule of Civil Procedure 50(a), the court "may only render judgment as a matter of law where 'the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue.'" *Palasota v. Haggard Clothing, Co.*, 499 F.3d 474, 480 (5th Cir. 2007)(citing Fed. R. Civ. P. 50(a)). "In entertaining a Rule 50 motion for judgment as a matter of law [the court] must review all of the evidence in the record, draw all reasonable inferences in favor of the nonmoving party, and may not make determinations or weigh the evidence." *Id.* (citing *Ellis v. Weasler Eng'g Inc.*, 258 F.3d 326, 337 (5th Cir. 2001)). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Id.* (citing *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 151 (2000)). The court must "disregard all evidence favorable to the moving party that the jury is not required to believe." *Id.* (citing *Ellis*, 258 F.3d at 337).

### **IV. Issues to be Decided**

BSC asks the court to resolve the following issues:

1. Whether the court properly construed the claims.
2. Whether BSC is entitled to judgment as a matter of law (“JMOL”) that it has not directly or contributorily infringed the Asserted Claims.
3. Whether BSC is entitled to JMOL that the Asserted Claims are invalid.
4. Whether BSC is, in the alternative, entitled to a new trial.

## **V. Analysis**

### **A. Claim Construction**

As an initial matter, claim construction is so intertwined with BSC’s JMOL arguments that the court must revisit claim construction before it can substantively address BSC’s JMOL arguments. “BSC is effectively seeking JMOL based on the constructions it previously proposed and the unconstrued terms.” Reply Brf.(#189) at 5. With that in mind, the court will first address claim construction.

The specific claim terms addressed by BSC in the Motion are as follows:<sup>1</sup>

Claim terms BSC asks the court to construe<sup>2</sup>

1. “fixation” in “flexible fixation device”
2. “capable of being shaped/shaping in three dimensions by manipulation by human hands”
3. “first major surface . . . adapted to be placed adjacent to a/the damaged tissue”
4. “second major surface . . . adapted to be placed opposite to the damaged tissue”

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<sup>1</sup> BSC summarized its positions in footnotes 1 and 2 of the Reply Brief.

<sup>2</sup> BSC argues that JMOL would be appropriate even if the court did not construe these terms.

5. “flexible in three dimensions by manipulation by human hands”

Claim terms for which BSC asks the court to alter its constructions<sup>3</sup>

6. The term “material release means”

7. “layer of flexible material that is minimally porous to macromolecules” and “device”

See Reply Brf. at fn 1 and fn 2.<sup>4</sup>

**(i). “fixation” in “flexible fixation device”**

BSC argues that the court did not construe “fixation.” This is misleading. The court accepted the parties’ agreed construction of “affixed to a fixation device.” See *Markman* Order at 6. The parties agreed to define “affixed to a fixation device” as “attached to a device capable of providing support.” Therefore, the parties defined “fixation” to mean “capable of providing support.” BSC now argues, without support, that “fixation device” has a different meaning when used in a different limitation. BSC’s arguments concerning “fixation” exemplify BSC’s claim construction positions

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<sup>3</sup>BSC addressed terms 8-9 nominally, but not substantively, in footnote 2. Nevertheless, the court will address those terms.

<sup>4</sup>BSC also asks the court to compare at least five of the claim terms to the accused products to construe those terms. Specifically, BSC states:

For terms (i) to (v), which the Court did not construe, BSC’s position is that the *constructions* BSC previously proposed are not substantively different from the *unconstrued terms* when the latter are properly *compared with the accused product*.

Reply Brf at fn 1 (emphasis added).

BSC effectively asks the court to conduct an infringement analysis rather than a claim construction analysis. The law is clear that the court must construe the claims of a patent first. Then, the court (or jury) must compare the accused products to the properly construed claims. “The first step is a question of law and the second step is a question of fact.” *Warner-Lambert Co. v. Teva Pharmaceuticals USA, Inc.*, 418 F.3d 1326 (Fed. Cir. 2005)(internal citations omitted).

throughout this case. Despite its agreement, BSC now asks the court to adopt its initial proposed construction for “fixation”—a construction BSC earlier abandoned. BSC asks the court to construe “fixation” to mean capable of “fixing” damaged tissue and further argues that “fixing” damaged tissue means “capable of holding such tissue in place.”

BSC’s claim construction position is untenable and improper. First, BSC agreed to a definition of “fixation” and that definition is “capable of providing support.” The record does not support construing “fixation device” using two different definitions. This is particularly problematic for dependent claim 6. Claim 6 depends from claim 1, (where “flexible fixation device” appears in the preamble) and BSC’s proposal has the effect that “fixation device” means two different things within the same claim. Secondly, neither the record nor the plain meaning of “fixing damaged tissue” support construing the term to mean “capable of holding such tissue in place.” The court resolved all disputes regarding the claim scope when the court rejected BSC’s proposed limitation(s).

**(ii). “layer capable of being shaped/shaping in three dimensions by manipulation by human hands” and “flexible in three dimensions by manipulation by human hands”**

In the parties’ claim construction briefing, Saffran argued that this term did not need construction, while BSC asked the court to construe the term to mean that the layer must be of suitable size, dimensions, and properties to permit alteration of the layer into a three dimensional shape by direct human handling. The court declined to construe the term because the court believed, and still believes, that the term is not ambiguous. Additionally, the record does not support adding the limitation “direct” into the claim and the phrases “suitable size, shape, and properties” are more ambiguous than the claim term and do not appear in the record. Moreover, the court had/has no

basis in the record for selecting one of multiple extrinsic dictionary definitions.

**(iii). “first major surface . . . adapted to be placed adjacent to a/the damaged tissue”/ “second major surface . . . adapted to be placed opposite to the damaged tissue”**

BSC argues that either the “material release means” or the phrase “adapted to” requires treating material to be placed on the “first major surface” but not the “second major surface.” However, BSC does not provide support in the record for identifying which of those claim terms impose(s) these requirements. BSC also incorporates the “adapted to” argument from its motion for summary judgment of non-infringement.<sup>5</sup>

In the parties’ claim construction briefing, Saffran argued that the “first major surface” and “second major surface” limitations did not need to be construed. BSC argued that the claim terms meant “a surface of the layer having two principle[sic] dimensions” and “a surface of the layer having two principle[sic] dimensions, opposite the first major surface and separated from the first major surface by a distance equal to the depth of the layer,” respectively. *See* Defendant’s Responsive Claim Construction Brief at 29. BSC then altered the proposal in its Motion for Summary Judgment of Non-Infringement:

the first major surface of the layer with treating material affixed thereto to be placed adjacent to a damaged tissue; and

second major surface of the layer with no treating material affixed thereto to be placed opposite the damaged tissue

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<sup>5</sup>BSC incorporates multiple arguments by reference into this motion. Procedurally, this eviscerates the court’s page limit restriction. BSC did not ask for, nor did the court grant, leave to incorporate more than 100 pages of argument by reference. Moreover, by incorporating arguments by reference without specifically identifying them, BSC leaves the court to speculate which specific arguments BSC intended to incorporate into the Motion.

Motion for Summary Judgment of Non-Infringement (#69) at 21.

BSC's claim construction proposal in the Motion is different from its proposed construction at the *Markman* Hearing and different from the proposal in its Motion for Summary Judgment of Non-Infringement. At the claim construction hearing, the parties only disputed the terms "first major surface" and "second major surface." *See, e.g.*, Defendant's Responsive Claim Construction Brief at 29. BSC effectively eliminated "adapted" from the claim language. Specifically, BSC offered the following constructions for "adapted to be placed adjacent to a/the damaged tissue" and "placing the device adjacent to a tissue/damaged tissue":<sup>6</sup>

the first major surface of the layer being placed facing the damaged tissue; and  
the first major surface of the layer being placed facing the damaged tissue.

Defendant's Responsive Claim Construction Brief at 36.

As mentioned above, Saffran argued that "first major surface" and "second major surface" needed no construction. BSC argued that the common meaning of "surface" connoted two "principle[sic] dimensions." BSC cited figure 1(c) and 9: 62-65 as support for this argument. The court agreed with Saffran that "first major surface" and "second major surface" needed no construction. BSC's proposed constructions created ambiguity, likely would have confused the jury, and lacked support in the record. BSC's current proposal is improper because (a) the claim term's plain language is unambiguous; (b) further limiting the claim term is not supported by the record; and (c) there is no basis in the intrinsic record for selecting one of many extrinsic dictionary definitions. Claim construction "is not an obligatory exercise in redundancy." *U.S. Surgical Corp.*

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BSC now links the "adapted to. . ." language with the "first major surface" and "second major surface" language. In its claim construction briefing, BSC treated these terms as separate claim terms.



*v. Ehicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). “[D]istrict courts are not (and should not be) required to construe every limitation present in a patent’s asserted claims.” *02 Micro International Ltd. v. Beyond Innovation Technology Co.* No. 2007-1302 (Fed. Cir. 2008)(slip copy)(emphasis in original).

**(iv). “material release means”**

In the Motion, BSC takes issue with the court’s construction of the recited structure for performing the claimed function of releasing the treating material toward the damaged tissue. The court construed the structure for performing the claimed function to be chemical bonds and linkages. BSC now asks the court to further limit “chemical bonds” to encompass “only bonds between atoms within a molecule.” This claim construction issue was not raised in BSC’s Request for Supplemental Claim Construction.

In the Motion, BSC cites to the trial transcript of expert testimony to say that the bonds specifically addressed in the specification are bonds between atoms within a molecule. BSC uses this extrinsic evidence to erase language from the specification identifying the bonds and linkages to be used in conjunction with the function of releasing the treating material toward the damaged tissue. *See e.g.*, 15:6-20, 22:4-17; 14:58-15:5. Another example of language that BSC asks the court to erase from the specification is the language at 15:6-20:

This device can be manufactured with several different medicines, each with their own particular release bond. Remarkably, one can implant the device of this invention such that one medicine is released by enzymes from Neutrophils (the first inflammatory cells to arrive), a second medicine released by enzymes from fibroblasts (cells that arrive later), and a third medicine which can be released only by osteoblasts (cells arriving even later). Although I have disclosed the implementation of multiple medicines in my application for the Malleable Fracture Stabilization Device with Micropores, the surprising specificity of medicine release provided by the chemical bond is entirely new and unexpected. The above-described feature of specific drug release is impossible using the prior art, and it represents

a major advance in fracture treatment.

15:6-20

Elsewhere, the specification states:

The rate of healing can be further accelerated by the attachment of a treating material, either mechanically or by chemical bond, to the inner surface of the device. The method of medicine release by chemical bond is also a method of highly significant improvement over the prior art. Prior art references all rely on the efflux of treating materials from micropores to deliver medicine. The ability to release medicine according to a rate constant, rather than relying on random efflux of molecules from various sized micropores, provide a surprising consistency to drug delivery not before seen in the art. Moreover, the chemical coupling of medicine and device provides for unprecedented specificity of release. The unexpected ability to be able to link medicine release with the specific enzymatic activity of healing cells is a highly significant improvement over the prior art.

22:4-17

In the Defendant's Responsive Claim Construction Brief, BSC identified the structure for the means plus function claim limitation as "the previously described layer, (which, as manufactured, has pores smaller than an at least one treating material such that the layer is impermeable to that treating material), wherein that treating material is initially affixed to the first major surface, but not to the second major surface." The court would have had to ignore language from the specification to adopt that construction which is improper as a matter of law. Now, BSC asks the court to further limit "chemical bonds" and to exclude bonds that are explicitly linked to the claimed function. The record does not support any of BSC's proposed constructions for these terms.

**(v). "device"**

BSC informs the court that "device" should be interpreted to mean "sheet." This is the same position that BSC took during claim construction before the court issued the Markman Order. In BSC's responsive claim construction brief, BSC quoted only a portion of the following passage from

the '760 patent specification:

[t]his invention is to be provided as a flexible sheet, spray or tube that the surgeon in the operating room can staple, suture or otherwise...

Col. 6, at ll. 49-50.

BSC omitted the language following “flexible sheet.” *See* Resp. Claim Constr. Brf. at 17. BSC addressed specific embodiments of the patented invention in which the “device” is a sheet. However, BSC ignored the other embodiments described and identified in the specification in which the “layer” or “device” is not a sheet. In fact, BSC *affirmatively misrepresented* the record to the court in its briefing. BSC represented to the court that:

the '760 patent describes and depicts no other embodiments of the device other than a sheet

Resp. Claim Constr. Brf. At 18.

The court may not construe a claim term so that it excludes embodiments clearly described in the specification, which is what the court would have had to do to adopt BSC's proposed construction for “device”—whether in the *Markman* Order or at this stage of the case. Consequently, the court concluded that “device” should be interpreted pursuant to its common and ordinary meaning. The court chose not to improperly limit “device” by importing limitations from the specification or to distort its plain meaning by choosing one of many dictionary definitions with no basis for making that particular choice when the term itself would be clearly understood by the jury—particularly in this instance where there are multiple limitations defining “device” in the claims.

## **B. JMOL Arguments**

Having addressed the claim construction positions, the court now addresses the JMOL arguments. BSC argued many bases for granting JMOL of non-infringement. The court will address

each argument individually.

**(I). JMOL that BSC Does Not Infringe Claims 1-4, and 6-7 Because the Taxus Products Do Not Meet the “Fixation” Device Limitation**

“Flexible fixation device” appears in the preamble of the claim 1. The preamble may limit the claim if the preamble is necessary to give life, meaning, and vitality to the claim or if it provides an antecedent basis for claim terms. *See MBO Labs, Inc. v. Becton, Dickson, & Co.*, 474 F.3d 1323, 1330 (Fed. Cir. 1998); *see also Bell Commc’ns Research, Inc. v. Vitalink Commc’ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995).

There are roughly six limitations that define the “flexible fixation device” identified in the preamble to claim 1. BSC’s only argument for making “flexible fixation device” a claim limitation is that it provides an antecedent basis for the term “device.” The court declined to read “flexible fixation device” as a positive limitation during claim construction and declines to do so at this time. “Flexible fixation device” does not give life, meaning, or vitality to the claim and does not provide an antecedent basis for the claim term “device.” BSC does not provide adequate justification to the court for deviating from the general rule that terms in the preamble are not positive limitations.

Even if the court determined that “flexible fixation device” is a positive limitation, granting JMOL that the Taxus Stents do not meet that limitation would be improper. The basis for BSC’s argument that the Taxus Stents do not meet this limitation is that a “fixation” device must be capable of “fixing” damaged tissue, “meaning that it must be capable of holding such tissue in place.” *See* Motion at 3. In making this argument BSC asks the court to modify its previous construction of “fixation”—a construction that the court adopted pursuant BSC’s agreement. Further, BSC’s new proposal is not supported by the record. As previously indicated, there is no support in the record

for defining “fixation device” such that it must be capable of fixing damaged tissue. Similarly, there is no basis in the record for determining that “fixing damaged tissue” means “holding damaged tissue in place.”

**(ii). JMOL that the Taxus Stents Do Not Infringe the Asserted Claims**

**Because the Taxus Products Do Not Meet the “Device” Limitation**

BSC’s argument rests on defining “device” to mean a sheet. For the reasons already discussed, “device” includes, but is not limited to, a sheet. There is sufficient evidence in the record to support the jury’s finding that the Taxus Stents satisfy the “device” limitation. *See, e.g., 2/5/08 A.M. Tr.; 2/5/08 Tr.; 2/6/08 A.M Tr.* There was expert and factual testimony from which the jury could have concluded that the Taxus Stents meet the “device” limitation. The court may not substitute its evaluation of the evidence for the jury’s verdict when ruling on a motion for JMOL, except when the jury’s verdict is not sufficiently supported by the evidence, which is not the case here.

**(iii). JMOL that BSC Does Not Infringe the Asserted Claims Because the**

**Taxus Stents do not Include a “Layer of Flexible Material that is Minimally Porous to Macromolecules”**

BSC states its argument as follows: “[a]s set forth in BSC’s previous submissions to the Court, BSC’s position is that this limitation cannot be satisfied by devices that allow healing macromolecules to escape from the damaged tissue because they have holes in them that are similar in size to the gaps between the struts of the open mesh prior art stents.” Motion at 5. This argument re-hashes a claim construction argument that the court has rejected. The court holds that the claimed invention is not limited to a sheet. BSC’s argument is that, as a matter of law, the invention is a

sheet and that if the gaps in the metal portions of the stent are uncovered and Macromolecules are allowed to flow between those gaps, then this limitation is not met. The patent does not prohibit or limit the flow of macromolecules between the gaps in the stents in all embodiments. The invention is the layer, not the stent itself. Moreover, the limitation requires the layer to be “minimally porous” not impermeable. As such, the court rejects BSC’s argument.

**(iv). JMOL that BSC Does Not Infringe the Asserted Claims Because the Taxus Stents Do Not Include a Layer “Capable of Being Shaped/Shaping in Three Dimensions by Manipulation by Human Hands”**

BSC argues that, as a matter of law, the Taxus Stents do not infringe because the coating cannot be manipulated directly by human hands.<sup>7</sup> BSC claims that it introduced undisputed evidence that the drug coating itself cannot be manipulated directly by human hands and also cited portions of the specification supporting its view. *See, e.g.*, 16:17-45; 15:50-61. BSC further argues that Saffran provided evidence showing that the coating was flexible, that a medical professional will manipulate the stent/catheter combination, and that Saffran showed a photo of bending a drug coated stent between one thumb and a forefinger. *See* Motion at 7. BSC claims that bending a drug coated stent between a thumb and a forefinger constitutes shaping in only two directions and that it is the stent, not the coating, that is being manipulated.

The court rejects these arguments. First, the drug coating is attached to the stent. Second,

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<sup>7</sup>These claim terms are sufficiently similar for the court to address them together. Indeed, BSC states that “the reasons why those proofs are not legally sufficient to show that the ‘flexible in three dimensions by manipulation by human hands’ limitation is satisfied are essentially the same as the reasons why those proofs are not legally sufficient to show that the ‘capable of being shaped in three dimensions by manipulation by human hands’ limitation is satisfied, which are discussed above.” Motion at 12.

the jury concluded that Saffran presented evidence showing that the layer on the Taxus Stents is capable of being shaped in three dimensions by manipulation by human hands. When considering a motion for JMOL, the court may not substitute its evaluation of the credibility of the evidence for the jury's verdict. One fact undisputed by BSC is that the coating of the Taxus Stents bends and flexes when the stents bend and flex. BSC's argument that compressing a Taxus Stent does not constitute shaping/bending three dimensionally by manipulation by human hands is a fact question that the jury resolved in favor of Saffran. Whether the court would conclude otherwise if placed in the jury's position is not the relevant issue in this analysis. Plaintiff's exhibit 108, which is a BSC document, shows the Taxus Stent, including the drug coating layer, traversing a curved blood vessel and expanding in three dimensions. *See also* PTX 124; PTX 98; PTX 109; and PTX 25. The court concludes that there is legally sufficient evidence in the record showing that the Taxus Stents meet these limitations.

**(v). JMOL that BSC Does Not Infringe the Asserted Claims Because the Taxus Stents Do Not Include a “a First Major Surface” that is “Adapted to be Placed Adjacent to a/the Damaged Tissue” and a “Second Major Surface” that is “Adapted to be Placed Opposite the Damaged Tissue”**

The construction of these claim terms has been discussed, so the court will not revisit that issue here. BSC concedes that the coating on the Taxus Stents includes a first and second major surface “just like any layer.” Motion at 14. BSC further argues in its reply to Saffran's opposition brief that both sides agreed that the coating completely surrounds each strut, so the conflict between the parties “arises solely from the fact that the parties dispute the scope of these limitations.” The court disagrees.

This is not a question of claim scope. As discussed above, there is no basis for limiting or further defining “first major surface” or “second major surface.” Moreover, the claim terms are unambiguous. Further “clarification” by the court would necessarily improperly limit the claim terms and likely create confusion. The court declined to construe these claim terms beyond their ordinary meaning because doing so would have required the court to read limitations into the claim terms that were not supported by the record and/or choose one dictionary definition out of multiple options with no suggestion or basis in the record for making that particular choice.

Additionally, BSC’s argument presupposes, *inter alia*, that the layer is a sheet. As already discussed, the layer is not limited to a sheet.

BSC makes a non-infringement argument that involves hypothetically unrolling the polymer layer from the Taxus stent. This argument was not raised at trial, the experts did not opine on this issue, and the fact witnesses offered no testimony on this point.

The jury was presented evidence and argument that the Taxus Stents include a layer meeting these claim limitations. Dr. Jamison testified that the first major surface of the polymer layer is the “surface adapted to be placed adjacent. . .” and that the second major surface of the polymer layer is the “surface adapted to be placed opposite . . .” *See* 2/5/08 P.M. Tr. 56:21-60:3; 67:12-69:15. Dr. Barry, BSC’s corporate representative, testified to the orientation of the surfaces of the polymer that would support the jury’s conclusion. He testified that, *inter alia*, the drug eluting polymer on the Taxus Stents has two surfaces, one facing the arterial tissue and one facing the lumen. *See* 2/6/08 A.M. Tr. at 5:14-8:06; 12:21-23; 14:15-15:02; 97:1-98:02-17.

BSC also argues that because the composition of the first and second major surfaces are the same, the first and second major surfaces constitute the same surface. The jury, however, could have



relied on Dr. Barry's testimony to reach a different conclusion. BSC simply disagrees with the jury's factual finding that the Taxus Stents meet this limitation. This disagreement is insufficient to warrant granting BSC JMOL.

**(vi). JMOL that BSC Does Not Infringe the Asserted Claims Because the Taxus Stents Do Not Include "Material Release Means for Release of an at Least One Treating Material in a Directional/Unidirectional Manner"**

As previously discussed, the court ruled that the treating material must be released "toward the damaged tissue." *Markman* Order at 8-9. Saffran used a number of pieces of evidence to try to meet his burden with respect to this limitation. One category of evidence used repeatedly by both sides was BSC's videos showing directional delivery of the paclitaxel, the treating material. *See, e.g.*, DTX 1080. BSC does not dispute that its videos show "all of the paclitaxel moving toward the vessel wall." *See* Motion at 14. However, BSC argues that "these materials are not sufficient to meet Dr. Saffran's burden either because, as BSC demonstrated without rebuttal, the materials were not designed to show the actual overall release pattern of paclitaxel, but rather were designed for other purposes." *Id.* BSC argues that it offered testimony and evidence showing that the paclitaxel released in a multi-directional manner rather than a uni-directional manner toward the damaged tissue.

Dr. Barry, BSC's corporate representative, testified that the BSC videos show all of the paclitaxel releasing toward the damaged tissue rather than releasing in a multi-directional manner. *See* 2/7/08 P.M. Tr. 51:1-52:1. Further, BSC provided no evidence of paclitaxel in the bloodstream, which would indicate a multi-directional delivery. *See e.g.*, 2-6-08 A.M. Tr. 21:05-28:24. Additionally, there is evidence in the record showing that BSC told the Food and Drug

Administration that BSC could not find paclitaxel in the bloodstream. *See e.g.*, PTX 23; PTX 29; PTX 52; PTX 53; PTX 54; PTX 62

This evidence presents a classic fact issue. BSC asks the court to disregard the fact that the jury viewed BSC documents and videos, listened to testimony, and believed that Saffran's characterization of the evidence was more credible than BSC's characterization. The court finds that the evidence supports the jury's finding that the Taxus Stents met the claimed functional limitation.

Next, the court addresses BSC's argument that it is entitled to JMOL that the Taxus Stents do not include the structure linked to the claimed function. The court has already addressed BSC's contention that the appropriate structure is "a layer that is impermeable to the treating material that has the treating material initially affixed to the first major surface, but not the second major surface, of the layer." *See Markman* Order at 9-10. BSC's proposed construction is not supported by the record.

BSC argues that only bonds between atoms within a molecule constitute a chemical bond. BSC cites to portions of the specification identifying such bonds, but ignores other portions of the specification where other bonds are linked to the claimed function. Saffran offered evidence that the chemical bonds and linkages identified in the specification, or equivalents thereof, were used in conjunction with the Taxus Stents. *See* 2/6/08 A.M. Tr. at 120; 2/11/08 A.M. Tr. 5:05-12:08; PTX 24; PTX 108; PTX 124.

BSC further argues that the Taxus Stents use a delivery mechanism that was disclaimed in the '760 patent. Specifically, BSC argues that the coating on the Taxus stents "is just like the prior art structure that the specification of the '760 patent indicates is not 'chemical bonds and linkages.'" Motion at 22. This argument is unpersuasive. First, as already noted, Saffran presented evidence

sufficient to enable the jury to conclude that the Taxus Stents use chemical bonds and linkages to release paclitaxel from the polymer. Moreover, the prosecution history does not indicate a complete disclaimer of diffusion as would be necessary to render JMOL under BSC's argument. Dr. Saffran distinguished prior art that did not use directional delivery, such as the Scott patent. *See e.g.*, 760 patent at 9:25-30.

Finally, BSC argues that Saffran did not properly compare the embodiments of the invention disclosed in the '760 patent with respect to this limitation to the accused products. The court disagrees with BSC. In his case in chief, Saffran provided evidence that the layer uses chemical bonds and linkages identified in the '760 patent. Dr. Freeman compared the Taxus Stents to the chemical bonds and linkages described in the '760 patent. *See, e.g.*, 2/6/08 A.M. Tr. 119:06-120:24; 118:03-07. In rebuttal, Dr. Freeman provided similar testimony. *See, e.g.*, 2/11/08 Tr. 5:05-16.

**(vii). JMOL that BSC Does Not Infringe the Asserted Claims Because the Taxus Stents Do Not Include a Device "Capable of Restricting/Substantially Restricting the Through Passage of at Least One Type of Macromolecule Therethrough"**

This is another version of an argument that BSC has made several times. BSC argues that this limitation is not met because there are gaps between the stents. The court has rejected BSC's request to limit the invention to a sheet. Consequently, BSC's argument for JMOL fails.

**(viii). JMOL that BSC Does Not Infringe Certain Asserted Dependent Claims Because No Jury Could Find that the Additional Limitations are Satisfied**

In this section, BSC argues that the Taxus Stents do not infringe claim 3, which requires

releasing at least one treating material by “lysis of a chemical bond” because there is no chemical bond between paclitaxel and the polymer in the coating. The court rejects this argument for the reasons it earlier found that there was sufficient evidence to support the jury’s conclusion that the Taxus Stents use a chemical bond to release the treating material.

BSC provides no substantive analysis in the Motion that the Taxus Stents do not infringe claims 9, 10, and 16. The court finds that Saffran provided evidence sufficient to justify the jury’s finding that the Taxus Stents infringe claims 9, 10, and 16.

**(ix). JMOL that BSC Does Not Contributorily Infringe the ‘760 Patent**

BSC argues that the jury incorrectly found BSC liable for contributory infringement because BSC sells the “entire subject matter” rather than a component of the infringing product and because Saffran did not prove that the Taxus Stents were not staples of commerce.

Saffran provided evidence to the jury demonstrating that the Taxus Stents are sold only to doctors or pursuant to a doctor’s instruction. *See* PTX 100. Further, Saffran presented evidence that the Taxus Stents’ use is limited to coronary arteries. *See* PTX 100.

With respect to the argument that BSC cannot be liable for indirect infringement because it sold the entire invention rather than components of the invention, the court rejects that argument. BSC sells the product to doctors who implant the device, which the jury concluded, infringes the ‘760 patent.

**(x). JMOL that the ‘760 Patent is Invalid Because It Fails the Written Description Requirement**

BSC argues that the Asserted Claims, except for claim 9, are invalid because they are broader than the invention described in the specification. The argument is that none of the Asserted

Claims besides claim 9 requires the claimed layer to allow small molecules to pass through it, but that the specification requires that limitation. BSC is asking the court to read the specification such that a preferred embodiment is the only embodiment described in the patent specification. Specifically, BSC asks the court to read the patent specification such that it requires the layer to be minimally porous to small molecules. The court cannot do that because it requires the court to limit the disclosure of the specification to only one of the embodiments described therein.

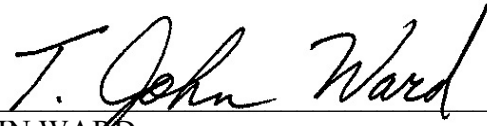
BSC also contends that the Asserted Claims should be invalid for failing to meet the written description requirement because the claims do not require the layer to be a sheet, they do not require a layer that has the treating material affixed to the first major surface, but not the second major surface, and because the claims do not require a layer that covers the gaps between stent struts when the layer is used in connection with a stent with struts. The court denies this request to enter JMOL because the specification's disclosure exceeds these particular embodiments.

## **V. CONCLUSION**

For the foregoing reasons, the court DENIES BSC's Motion for JMOL or, in the alternative, for a new trial. BSC proposed or suggested different claim constructions for the same claim terms at various stages of the trial. Moreover, these constructions were inconsistent with each other. If the court had adopted BSC's proposed constructions at one stage in the trial, then, according to BSC's later arguments, the court would have committed legal error.

The court finds that evidence in the record supports the jury's findings with respect to the issues raised in the Motion. BSC offered no argument for why it should be granted a new trial in the Motion. Therefore, the court DENIES the relief requested in the Motion.

SIGNED this 9th day of July, 2008.

A handwritten signature in black ink, reading "T. John Ward". The signature is written in a cursive style with a large, stylized "T" and "W".

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T. JOHN WARD  
UNITED STATES DISTRICT JUDGE